UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,115	03/31/2004	Darin G. Schaeffer	8627/331	6599

757 7590 10/24/2006

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER	
POUS, NATALIE R	
ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/815,115	SCHAEFFER ET AL.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/29/06, 3/31/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 4, 7, 8, 9, 12, 17, 18, 21-29, 32-34, 37, 42, 43 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Camrud et al. (US 6258117).

Regarding Claim 1, Camrud teaches an expandable stent comprising: a plurality of substantially cylindrical, serpentine ring structures (12, 14, 16, 18), wherein each ring

structure extends around a circumference of the stent and comprises at least one unit structure, wherein said at least one unit structure comprises a plurality of strut members and a plurality of bends, said strut members and bends forming a substantially zig-zag pattern (fig. 7a); and at least one connector (113) member joining two of said ring structures when said stent is in an unexpanded state, wherein said at least one connector member is biodegradable and adapted to biodegrade when said stent is in an expanded state so that said two ring structures become substantially disjoined (Column 1, proximate lines 30-39).

Regarding Claim 2, Camrud teaches the expandable stent of claim 1, wherein said stent is a substantially integral, tubular shape in said unexpanded state (Column 1, proximate lines 12-13).

Regarding Claim 4, Camrud teaches the expandable stent of claim 1, wherein said at least one connector member is made of one or more of polymers, copolymers, block polymers, poly-lactic acid, poly-glycolic acid, polyglycolides, polylactides, polycaprolactones, polyglycerol sebacate, polycarbonates, polyethylene oxide, polybutylene terepthalate, polydioxanones, hybrids, composites, collagen matrices with growth modulators, proteoglycans, glycosaminoglycans, vacuum formed small intestinal submucosa, fibers, chitin, and dextran (Column 9, proximate lines 14-22).

Regarding Claim 7, Camrud teaches the expandable stent of claim 1, wherein said at least one connector member (113) comprises one layer having a substantially uniform degradation rate.

Regarding Claim 8, Camrud teaches the expandable stent of claim 1, wherein said ring structures are made of one or more of nitinol, stainless steel, 316 L stainless steel, cobalt chromium, nickel titanium, platinum, and inconel (Column 5, proximate lines 55-60).

Regarding Claim 9, Camrud teaches the expandable stent of claim 1, wherein said ring structures comprise a non-biodegradable base material and one or more biodegradable coating layers (Column 5, proximate lines 34-53).

Regarding Claim 12, Camrud teaches the expandable stent of claim 9, wherein said ring structures comprise one biodegradable coating layer having a uniform degradation rate (Column 5, proximate lines 34-53).

Regarding Claim 17, Camrud teaches the expandable stent of claim 1, wherein said stent is one of self-expanding and balloon-expandable (Column 7, proximate lines 15-24).

Regarding Claim 18, Camrud teaches the expandable stent of claim 1, wherein when said at least one connector member biodegrades in an expanded state, said two ring structures become completely disjoined so that said stent does not form an integral structure (Column 2, proximate lines 48-50).

Regarding Claim 21, Camrud teaches the expandable stent of claim 1, wherein said at least one connector (108) member is curved.

Regarding Claim 22, Camrud teaches the expandable stent of claim 1, wherein said at least one connector member (90) is straight.

Regarding Claim 23, Camrud teaches the expandable stent of claim 1, wherein when said stent is in an unexpanded state said at least one connector (108) member has first (110) and second (112) ends, said first end being connected to one of said plurality of bends of one of said two ring structures and said second end being connected to another of said plurality of bends of the other of said two ring structures (fig. 7a).

Regarding Claim 24, Camrud teaches the expandable stent of claim 1, wherein when said stent is in an unexpanded state there are two or more connector members joining said two ring structures and adjacent connector members are circumferentially aligned (fig. 7a).

Regarding Claim 25, Camrud teaches the expandable stent of claim 1, wherein adjacent ring structures are axially aligned (fig. 7a).

Regarding Claim 26, Camrud teaches the expandable stent of claim 1, wherein a plurality of substantially straight tie-bars (126) join a plurality of said ring structures.

Regarding Claim 27, Camrud teaches method of expanding a stent comprising: providing an expandable stent which in an unexpanded state comprises a plurality of substantially cylindrical, serpentine ring structures (12, 14, 16, 18), wherein each ring structure extends around a circumference of the stent, and at least one biodegradable connector (113) member joining two of said ring structures; delivering the stent in an unexpanded state to a final destination within a mammalian body; expanding the stent; and biodegrading said at least one connector member so that said two ring structures

become substantially disjoined (Column 1, proximate lines 18-26 and Column 2, proximate lines 43-54).

Regarding Claim 28, Camrud teaches the method of claim 27 wherein, each ring structure extends around a circumference of the stent and comprises at least one unit structure, wherein said at least one unit structure comprises a plurality of strut members and a plurality of bends, said strut members and bends forming a substantially zig-zag pattern (fig. 7a).

Regarding Claim 29, Camrud teaches the method of claim 27, wherein said at least one connector member is made of one or more of polymers, copolymers, block polymers, poly-lactic acid, poly-glycolic acid, polyglycolides, polylactides, polycaprolactones, polyglycerol sebacate, polycarbonates, polyethylene oxide, polybutylene terepthalate, polydioxanones, hybrids, composites, collagen matrices with growth modulators, proteoglycans, glycosaminoglycans, vacuum formed small intestinal submucosa, fibers, chitin, and dextran (Column 9, proximate lines 14-22).

Regarding Claim 32, Camrud teacheshe method of claim 27, wherein said at least one connector member (113) comprises one layer having a substantially uniform degradation rate.

Regarding Claim 33, Camrud teaches the method of claim 27, wherein said ring structures are made of one or more of nitinol, stainless steel, 316 L stainless steel, cobalt chromium, nickel titanium, platinum, and inconel (Column 5, proximate lines 55-60).

Regarding Claim 34, Camrud teaches the method of claim 27, wherein said ring structures comprise a non-biodegradable base material and one or more biodegradable coating layers (Column 5, proximate lines 34-53).

Regarding Claim 37, Camrud teaches the method of claim 34, wherein said ring structures comprise one biodegradable coating layer having a uniform degradation rate (Column 5, proximate lines 34-53).

Regarding Claim 42, Camrud teaches the method of claim 27, wherein said stent is expanded using one of a self-expanding process and a balloon-expandable process (Column 7, proximate lines 15-24).

Regarding Claim 43, Camrud teaches the method of claim 27, wherein when said at least one connector member biodegrades in an expanded state, said two ring structures become completely disjoined so that said stent does not form an integral structure (Column 2, proximate lines 48-50).

Regarding Claim 47, Camrud teaches the method of claim 27, wherein said at least one connector member (90) is straight.

Claims 1, 20, 27, 45 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Camrud et al. (US 6485510).

Regarding Claim 1, Camrud teaches an expandable stent comprising: a plurality of substantially cylindrical, serpentine ring structures (12, 14, 16, 18), wherein each ring structure extends around a circumference of the stent and comprises at least one unit structure, wherein said at least one unit structure comprises a plurality of strut members

and a plurality of bends, said strut members and bends forming a substantially zig-zag pattern (fig. 7a); and at least one connector (113) member joining two of said ring structures when said stent is in an unexpanded state, wherein said at least one connector member is biodegradable and adapted to biodegrade when said stent is in an expanded state so that said two ring structures become substantially disjoined (Column 1, proximate lines 44-51).

Regarding Claim 20, Camrud teaches the expandable stent of claim 1, wherein said at least one connector member (215) is substantially U or V shaped.

Regarding Claim 27, Camrud teaches method of expanding a stent comprising: providing an expandable stent which in an unexpanded state comprises a plurality of substantially cylindrical, serpentine ring structures (12, 14, 16, 18), wherein each ring structure extends around a circumference of the stent, and at least one biodegradable connector (113) member joining two of said ring structures; delivering the stent in an unexpanded state to a final destination within a mammalian body; expanding the stent; and biodegrading said at least one connector member so that said two ring structures become substantially disjoined (Column 1, proximate lines 22-31 and Column 1, proximate lines 44-51).

Regarding Claim 45, Camrud teaches the method of claim 27, wherein said at least one connector member (215) is one of substantially U and V shaped.

Regarding Claim 46, Camrud teaches the method of claim 27, wherein said at least one connector member is curved (fig. 22).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 19 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Camrud (6258117) in view of Hong et al. (US 6565599).

Camrud '117 teaches all limitations of preceding dependent claims 1 and 27, as previously described, but fails to teach wherein said at least one connector member is flexible prior to the stent being expanded. Hong teaches a stent comprising radial sections connected by flexible links in order to provide longitudinal flexibility of the stent during deployment. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Camrud '117 with flexible links as taught by Hong in order to provide longitudinal flexibility of the stent during deployment.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Camrud (6258117) in view of Evans et al. (US 6102938).

Camrud '117 teaches all limitations of preceding dependent claim 1 as previously described, but fails to teach wherein said stent is substantially Y-shaped when in said unexpanded state. Evans teaches a stent having a Y-shaped configuration when in an unexpanded state (82) in order to provide a stent for use in the aortic and iliac arteries. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Camrud '117 with a Y-shaped configuration as taught by Evans in order to provide a stent for use in the aortic and iliac arteries.

Claims 13, 16, 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Camrud '117 in view of Wu et al. (US 6254632)
Camrud '117 teaches all limitations of preceding dependent claims 1 and 27 as previously described, and further teaches wherein the ring structures comprise a base material made of a combination of non-biodegradable materials and biodegradable materials (Column 5, proximate lines 34-53), but fails to teach wherein the biodegradable material is a polymer. Wu teaches a stent having a base material made of a combination of non-biodegradable material (114) and biodegradable polymer materials (420) in order to provide controlled release of a therapeutic substance (410). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Camrud '117 with a polymeric material as taught by Wu in order to provide controlled release of a therapeutic substance.

Claims 5, 10, 30 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Camrud '117 in view of Kocur (US 6350277).
Camrud '117 teaches all limitations of preceding dependent claims 1 and 17 as previously described, and further teaches wherein the connectors may degrade over a predetermined period of time (Column 5, proximate lines 27-33), but fails to teach wherein the connector member is adapted to biodegrade within thirty days to one-hundred eighty days after said stent is expanded. Kocur teaches a stent with a biodegradable portion that may degrade over a period of time of within thirty days to one-hundred eighty days after implementation (Columns 7 and 8, proximate lines 62-67, and 1-8 respectively) in order to allow for the desired degradation time whether it be quickly or delayed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the degradation time of within thirty days to one-hundred eighty days as taught by Kocur in order to allow for the desired degradation time whether it be quickly or delayed.

Claims 14, 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Camrud '117 and Wu as applied to claims 1, 13, 27 and 38 above, and further in view of Kocur. The combination of Camrud '117 and Wu teaches all limitations of preceding dependent claims 27 and 38 as described above, but fails to teach the method of biodegrading said polymers of said base material within thirty days to one-hundred eighty days after said stent is expanded. Kocur teaches a stent with a

biodegradable portion that may degrade over a period of time of within thirty days to one-hundred eighty days after implementation (Columns 7 and 8, proximate lines 62-67, and 1-8 respectively) in order to allow for the desired degradation time whether it be quickly or delayed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the degradation time of within thirty days to one-hundred eighty days as taught by Kocur in order to allow for the desired degradation time whether it be quickly or delayed.

Claims 6, 11, 31 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Camrud '117 in view of Sirhan et al. (US 7077859). Camrud teaches all limitations of preceding dependant claims 1, 9, 13, 27, and 34 as described previously, but fails to teach wherein the connector or coating layers are formed with layers having multiple biodegradable layers with different degradation rates. Sirhan teaches an implanted prosthesis having multiple biodegradable layers with different degradation rates in order to allow for programmed and controlled degradation of layers to achieve a desired purpose. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Camrud '117 with multiple layers having varying degradation rates in order to allow for programmed and controlled degradation of layers to achieve a desired purpose.

Claims 15 and 40 rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Camrud '117 Wu as applied to claims 1, 13, 38 and 40 above, and

further in view of Sirhan. The combination of Camrud '117 Wu teaches all limitations of claims 1, 13, 38 and 40 as described above, but fails tot each wherein the connector or coating layers are formed with layers having multiple biodegradable layers with different degradation rates. Sirhan teaches an implanted prosthesis having multiple biodegradable layers with different degradation rates in order to allow for programmed and controlled degradation of layers to achieve a desired purpose. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Camrud '117 and Wu with multiple layers having varying degradation rates in order to allow for programmed and controlled degradation of layers to achieve a desired purpose.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
10/17/06

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
10/20/06.